K080247
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510(k) Summary

Trade Name:	QuikClot® Nosebleed™
Device Class:	Class 1
Classification Panel:	General and Plastic Surgery
Common Name:	Hemostatic Gauze
Classification Name:	Dressing
Classification Code:	FRO
Predicate Device:	QuikClot® eX™ (K072474)
Submitted By:	Ronald E. Peterson, Dir. of Regulatory Affairs and QA
Company Name:	Z-Medica Corporation
Company Address:	4 Fairfield Blvd., Wallingford, CT 06492
Company Phone:	+1-203-294-0000 x262
Prepared:	January 28, 2008

Description of Device

The material composition of QuikClot® Nosebleed™ is identical to QuikClot® eX™. QuikClot® Nosebleed™ is a 2" x 2" four-ply Hemostatic Gauze and QuikClot® eX™ is a 4" x 4" four-ply Hemostatic Gauze Sponge.

Indications for Use

For temporary use to control minor nosebleeds.
(Over the Counter use)

Discussion of Data to Support Substantial Equivalence

QuikClot® Nosebleed™ is identical to QuikClot® eX™ in composition and hemostatic performance. QuikClot® Nosebleed™ differs from QuikClot® eX™ only in size of device and QuikClot® Nosebleed™ has specific instructions for the nosebleed indication.

Conclusion

Based on the device description and the specific labeling, QuikClot® Nosebleed™ is substantially equivalent to the predicate device and is safe and effective when temporarily used to stop minor nosebleeds.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN - 4 2010

Z-Medica Corporation
% Ms. Mary McNamara-Cullinane
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K080247
Trade/Device Name: QuickClot® Nosebleed™
Regulatory Class: Unclassified
Regulation Name: Dressing
Product Code: FRO
Dated: January 23, 2008
Received: January 30, 2008

Dear Ms. McNamara-Cullinane:

This letter corrects our substantially equivalent letter of February 27, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other

requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Proposed Indications for Use

510(k) Number (if known): K080247

Device Trade Names: QuikClot® Nosebleed™

Device Common Name: Hemostatic Gauze

Indications for Use:

QuikClot® Nosebleed™ is intended for temporary use to control minor nosebleeds in children over 12 years of age and adults.

Prescription Use ☐ AND/OR Over-The-Counter Use ☑

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K080247